

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NORTH CAROLINA  
SOUTHERN DIVISION

No. 7:22-cv-00073-M

CENTER FOR ENVIRONMENTAL  
HEALTH, *et al.*,

Plaintiffs,

v.

MICHAEL REGAN,<sup>1</sup> in his official  
capacity as Administrator of the U.S.  
Environmental Protection Agency, *et al.*,

Defendants.

**REPLY IN SUPPORT OF  
MOTION TO DISMISS**

As EPA's Motion to Dismiss ("EPA Mot.", Dkt. Nos. 48-49) explains, this Court lacks jurisdiction to hear Plaintiffs' Amended Complaint. Plaintiffs' Opposition ("Plfs.' Opp.", Dkt. No. 52) offers no persuasive argument otherwise.

*First*, contrary to Plaintiffs' characterization, EPA in fact "granted" Plaintiffs' petition. That EPA's intended proceeding is not identical to every aspect of Plaintiffs' petition does not render it a "denial."

*Second*, to what extent EPA is commencing an "appropriate proceeding" is not relevant to the question of whether EPA in fact "granted" Plaintiffs' petition. And even if it was, the proceeding that EPA is commencing is entirely appropriate and within its discretion. There is no additional relief the Court can grant Plaintiffs.

---

<sup>1</sup> EPA Administrator Michael Regan is automatically substituted for Jane Nishida pursuant to Rule 25(d) of the Federal Rules of Civil Procedure.

*Third*, Plaintiffs now adopt a litigation position that is inconsistent with their petition. Their petition offered only general assertions that PFAS “as a class” may present “an unreasonable risk of injury to health or the environment.” Yet now, they demand that EPA should have individually scrutinized each of the identified 54 substances (and proposed mixtures and epidemiological studies) and agreed to issue individual test orders for each of these proposals.

*Fourth*, Plaintiffs’ concern that EPA labeled its December 2021 decision as a “grant” to avoid judicial review is unfounded. TSCA and other statutes offer other avenues for review of final agency action, which further demonstrates the inappropriateness of judicial review here, where EPA’s proceedings with respect to the issues raised in Plaintiffs’ petition are ongoing and subject to change.

*In conclusion*, because EPA granted Plaintiffs’ petition, the Court lacks subject-matter jurisdiction to consider Plaintiffs’ Amended Complaint.

#### **I. EPA Granted the Petition, and the Court Lacks Jurisdiction.**

The Court lacks jurisdiction because EPA granted the petition. *See* EPA Mot. 14-19. Plaintiffs’ argument that EPA’s action was in fact a “denial” because EPA declined to commit to “all of the requests for testing in the petition” is wrong. Plfs.’ Opp. 16; *see also id.* at 10-11; 21-23 (noting that EPA should have agreed to issue testing orders for each of the 54 individual substances identified in the petition).

Plaintiffs cited no authority to support their proposition that EPA, in granting a TSCA Section 21 petition, must also agree to all (or even a majority) of the measures proposed by a petitioner. Indeed, a petitioner can only request EPA to “initiate a

proceeding” under the relevant section of TSCA (in this case, TSCA Section 4). 15 U.S.C. § 2620(a) (“Any person may petition [EPA] to *initiate* a proceeding . . . .” (emphasis added)); EPA Mot. 15-17. Plaintiffs petitioned EPA to issue a test order to fill certain information gaps with respect to certain purported PFAS. EPA granted their petition and is commencing appropriate proceedings under Section 4 to address PFAS information gaps. EPA Mot. 6-10. Nothing in the statute suggests that a petitioner can both request the initiation of a TSCA proceeding *and* mandate what a proceeding’s outcome would look like. In fact, the statutory text affords EPA broad discretion to “commence an appropriate proceeding” upon granting a petition. *See* 15 U.S.C. § 2620(b)(3). Plaintiffs’ unsupported proposition would eliminate EPA’s discretion by allowing any plaintiff to claim EPA “denied” its petition merely because EPA did not commit to every proposal in a petition.

Moreover, Plaintiffs’ view is inconsistent with other aspects of the statute. Petitions must “set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal” a rule or order. *Id.* § 2620(b)(1). The petition at issue asserted that certain PFAS, “as a class,” met the criteria for Section 4 testing—generally speaking, that they may present an unreasonable risk, that there are information gaps, and that testing is necessary to fill those gaps. *See* EPA Mot. 3–4; Pet. 8, 17 (Dkt. No. 49-1). The statute does not necessarily require that a petitioner also enumerate in its Section 21 petition specific testing proposals to fill asserted information gaps. Where, as here, a petitioner volunteers those proposals, EPA’s decision to grant the petition by commencing an appropriate proceeding that does not

exactly mirror such proposals does not render the agency decision a “denial.” To hold otherwise would allow citizen petitioners, rather than EPA, to direct the administrative process under TSCA, which requires that EPA consider several specific factors when issuing testing orders under Section 4. *See* EPA Mot. 15–17. The Court should reject Plaintiffs’ argument.

## **II. EPA is Commencing “Appropriate Proceedings.”**

Plaintiffs next argue that the actions that EPA intends to take in carrying out its grant of Plaintiffs’ petition do not constitute an “appropriate” proceeding under TSCA because, in their view, EPA only committed to issuing testing orders on 7 of the 54 substances identified in their petition while stating an intent to rely on representative or deferred testing samples for the remaining substances. *See* Plfs.’ Opp. 24. This interpretation is unavailing and ignores EPA’s wide discretion in how it carries out its responsibilities under TSCA.

As an initial matter, Plaintiffs’ position mischaracterizes EPA’s petition response. Plaintiffs’ claim rests on the belief that EPA has “refused to issue” the tests requested and “closed the door” on many aspects of Plaintiffs’ proposed protocol. Plfs.’ Opp. 10, 24. EPA’s petition response, however, notes that as it gathers more information, the chemical substances identified as candidates for testing and the tests required may change over time. Dec. 2021 Resp. 10, 15 (Dkt. No. 49-2). EPA articulated in its petition response what it believes the appropriate proceeding may entail. Indeed, the implementation of EPA’s PFAS Testing Strategy itself is ongoing and subject to change.

Further, and fundamentally, whether EPA is conducting an “appropriate proceeding” under Section 21 is not reviewable under TSCA’s Section 21 judicial review provision. “Judicial review provisions [] are jurisdictional in nature and must be construed with strict fidelity to their terms.” *Stone v. I.N.S.*, 514 U.S. 386, 405 (1995). Here, the judicial review provision under Section 21 is limited to whether EPA should be compelled to initiate a Section 4 proceeding regarding PFAS, which EPA agreed to do. *See* 15 U.S.C. § 2620(b)(4)(A). Whether EPA is commencing an “appropriate proceeding” is beyond the scope of review available under Section 21. Moreover, as Plaintiffs also suggest, whether EPA is commencing an “appropriate proceeding” is generally irrelevant to the threshold question of whether EPA granted Plaintiffs’ petition. Plfs.’ Opp. 23.

In any event, EPA’s anticipated proceeding following the grant of Plaintiffs’ petition is entirely appropriate. An agency “enjoys broad discretion in determining how best to handle related, yet discrete, issues in terms of procedures and priorities.” *Ctr. for Biological Diversity v. Jackson*, 815 F. Supp. 2d 85, 94 (D.D.C. 2011) (quoting *Mobil Oil Exploration & Producing Se. v. United Distrib. Cos.*, 498 U.S. 211, 230 (1991)). And how EPA conducts an “appropriate proceeding” in response to a grant of a Section 21 petition containing multiple, closely related issues is well within its discretion. *See Jackson*, 815 F. Supp. 2d at 94 (“EPA has expertise in handling TSCA petitions, and the Court finds that it should defer to the Agency’s determination of the most efficient way to address rulemaking documents.”). Such discretion is especially warranted given EPA’s expertise in managing its regulatory duties,

including whether to handle administrative requests together or separately. *Cf. Collins v. Nat'l Transp. Safety Bd.*, 351 F.3d 1246, 1253 (D.C. Cir. 2003) (deferring to Coast Guard's application of rules for licensing of pilots based on the agency's "expertise . . . in deciding the most efficient way to administer its licensing and discipline procedures").

Here, (although EPA was not required to do so) EPA provided ample justification for why its anticipated actions constitute an "appropriate" proceeding under TSCA. EPA described how TSCA requires a tiered screening and testing process, under which the results of screening-level tests or assessments of available information will then inform EPA's decision as to whether one or more additional tests are necessary. Dec. 2021 Resp. 12; *see also* 15 U.S.C. § 2603(a)(4). EPA also explained that TSCA requires EPA to reduce and replace the use of vertebrate animals in testing, in part, by requiring consideration of a category-based approach to understanding the potential health and environmental effects of PFAS. *Id.* § 2603(h)(1)(B)(ii); Dec. 2021 Resp. 10-12. Rather than directly issue test orders for each of the 54 substances in question, TSCA compels EPA to consider using categories when requiring testing, which is what EPA determined is appropriate here. Dec. 2021 Resp. 10-12.

Ultimately, to treat Plaintiffs' petition as multiple separate requests for test orders and require EPA to consider issuing test orders for each of the 54 substances identified by Plaintiffs (along with Plaintiffs' proposed mixtures and epidemiological test order requests) would force EPA to treat each of the petition's individual

proposals as separate and discrete requests for test orders. This would not only disrupt the statutory directive in TSCA (15 U.S.C. § 2603(h)(1)(B)(ii)) that calls for EPA to consider grouping related substances in scientifically appropriate categories for testing, it would result in an inefficient administrative process under which EPA would be required to consider individual Section 4 testing orders for closely related substances, whose hazards or health outcomes can otherwise be readily understood using a categorical approach. *See also Jackson*, 815 F. Supp. 2d at 94.

Accordingly, even if the Court had jurisdiction to hear Plaintiffs' claims, the Court cannot grant any relief beyond what EPA has already agreed to do—commence an “appropriate proceeding” in accordance with TSCA Section 21. 15 U.S.C. § 2620(b)(3). EPA has strong justification for why its intended proceeding is “appropriate” here. The Court cannot order any further relief, and the case is moot.<sup>2</sup>

### **III. Plaintiffs Adopt a Litigation Position that Is Inconsistent with Their Petition.**

Moreover, the substance of Plaintiffs' petition, which only asserts that PFAS “as a class” may present an unreasonable risk, ultimately offers further support that EPA's category-based approach toward PFAS testing is entirely appropriate. Plaintiffs argue that for EPA's action on the petition to be considered a “grant” of the petition, EPA is required to issue Section 4 test orders for each of the 54 identified substances (along with mixtures and epidemiological studies). Pls.' Opp. 21-23.

---

<sup>2</sup> Plaintiffs concede that their claims against EPA's initial January 7, 2021 denial of Plaintiffs' citizen petition is now moot in light of EPA's reconsideration and December 2021 response. Plfs.' Opp. 16 n.5.

Plaintiffs further say that EPA’s December 2021 response “did not dispute plaintiffs’ showings that the 54 PFAS met the criteria for testing in Section 4(a)(1) of TSCA.” *Id.* at 10. Yet, Plaintiffs’ petition made no attempt to demonstrate that each of the 54 individual chemical substances *individually* meets the criteria for test orders under Section 4(a)(1). *See* 15 U.S.C. § 2603(a)(1)(A)(i) (Section 4 requires EPA to mandate testing of a chemical substance or mixture if EPA finds that it may present “an unreasonable risk of injury to health or the environment.”). Rather, their petition generally asserts that PFAS “as a class” may present “an unreasonable risk of injury to health or the environment.” *See* Pet. 16-18. It is telling that even Plaintiffs view the 54 identified substances as so closely related that their petition makes no effort to show how each of the 54 substances *individually* meet the “may present an unreasonable risk” standard under Section 4.

Plaintiffs want it both ways. They say that their petition’s general assertion that PFAS “as a class” may present unreasonable risks is sufficient to support issuance of individual test orders for each of the 54 identified substances. Yet, they also argue that a PFAS testing strategy based on PFAS categories is not sufficient to obtain information about the 54 substances. These two positions cannot be reconciled.

#### **IV. While the Court Lacks Subject-Matter Jurisdiction to Hear Plaintiffs’ Amended Complaint, Plaintiffs May Have Other Future Opportunities for Judicial Review.**

Plaintiffs contend that if this Court were to dismiss their Amended Complaint, it “would negate the purposes of Section 21 by precluding citizen access to judicial remedies” and allow EPA to “avoid any judicial accountability” with respect to its



response to Plaintiffs' petition. Plfs.' Opp. 15. This argument, however, ignores the other sections of TSCA that offer any person the opportunity to seek judicial review of a final Section 4 test rule or order or to file suit to compel EPA to perform a non-discretionary duty under TSCA. The Administrative Procedure Act ("APA") also allows a party to bring a claim to compel agency action that is unreasonably delayed where the statutory duty imposed is a general duty of timeliness. In other words, if this proceeding were dismissed, it is possible that in the future, Plaintiffs may have other more appropriate opportunities to seek judicial review regarding the issues set forth in their Amended Complaint.

Indeed, TSCA contains multiple potential avenues for judicial relief beyond Section 21. For example, Section 20 of TSCA provides that (subject to certain limitations) any person may commence an action against the EPA to compel it "to perform any act or duty under this chapter which is not discretionary." 15 U.S.C. § 2619(a)(2). TSCA Section 19's judicial review provision provides that "not later than 60 days after the date on which a rule is promulgated under [Section 4], or the date on which an order is issued under [Section 4 . . .] of this title, any person may file a petition for judicial review of such rule or order with the United States Court of Appeals . . ." 15 U.S.C. § 2618(a)(1)(A).

Reading these judicial review provisions together provides a more complete picture of how Congress intended judicial review to function in the context of TSCA's citizen petition process. Section 21's judicial review provision offers the opportunity for a petitioner to challenge the front end of the petition process by providing for

judicial review of EPA's refusal to *initiate* a proceeding for a rule or order under TSCA. But it does not allow for a citizen to demand the specific outcome of that proceeding. *See Citizens for a Better Env't v. Thomas*, 704 F. Supp. 149, 152 (N.D. Ill. 1989). For a petitioner, TSCA Section 19 provides an opportunity for judicial review at the back end of the petition process, allowing anyone (assuming all constitutional and statutory pre-requisites are met) to challenge any final rules or orders issued by EPA under TSCA. 15 U.S.C. § 2618(a)(1)(A). Section 20 allows for suits against EPA to compel it to perform a non-discretionary act under TSCA. 15 U.S.C. § 2619(a)(2).

And under 5 U.S.C. § 706(1) of the APA, a party can bring a claim for “unreasonable delay” “when a statute grants some degree of discretion to an agency as to the timing of a required action, thereby imposing merely a general duty of timeliness.” *Conservation Force v. Salazar*, 753 F. Supp. 2d 29, 34-35 (D.D.C. 2010), *aff'd*, 699 F.3d 538 (D.C. Cir. 2012) (internal quotations omitted).

Plaintiffs complain that EPA has not yet provided a “timetable” for its anticipated test orders for representative substances and they characterize EPA's planned proceeding as vague and open-ended. Plfs.' Opp. 24. But that is precisely why it is inappropriate to hear Plaintiffs' claims now when EPA has only communicated its anticipated plans. Ultimately, the appropriate course of action would be for EPA to pursue appropriate proceedings in response to granting Plaintiffs' petition. To be sure, EPA reserves the right to challenge any future action seeking judicial review. But where EPA has granted Plaintiffs' petition and has only begun to commence the appropriate administrative process, Plaintiffs' suit should be dismissed.

This 15th day of August 2022.

Respectfully submitted,

TODD KIM  
Assistant Attorney General

/s/ Hubert T. Lee

HUBERT T. LEE  
BRANDON N. ADKINS  
U.S. Department of Justice  
Environment & Natural Resources Division  
Environmental Defense Section  
4 Constitution Square  
150 M Street, NE, Suite 4.1116  
Washington, D.C. 20002  
(202) 514-1806 (Lee)  
(202) 616-9174 (Adkins)  
Fax (202) 514-8865  
Hubert.lee@usdoj.gov  
Brandon.adkins@usdoj.gov  
Lee: NY Bar #4992145  
Adkins: DC Bar #1010947

MICHAEL F. EASLEY, JR.  
United States Attorney

C. MICHAEL ANDERSON  
Assistant United States Attorney  
150 Fayetteville Street, Suite 2100  
Raleigh, N.C. 27601  
(919) 856-4530  
Fax (919) 856-4821  
Michael.anderson7@usdoj.gov  
N.C. Bar No. 42646

*Counsel for Defendants*

## **CERTIFICATE OF SERVICE**

I hereby certify that on August 15, 2022, I electronically transmitted the foregoing to the Clerk of Court using the ECF system for filing and transmittal of a Notice of Electronic Filing to registered counsel for all parties.

/s/ Hubert T. Lee